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Roxane Laboratories, Incorporated*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

PROMETHEUS LABORATORIES, INC.,

Plaintiff,

v.

ROXANE LABORATORIES, INC.,

Defendant.

Civil Action No. 2:11-CV-00230-FSH-PS

**ROXANE LABORATORIES, INC.’S
ANSWER TO PLAINTIFF’S
COMPLAINT FOR PATENT
INFRINGEMENT**

For its answer to the complaint filed on January 14, 2011 (the “Complaint”) by Prometheus Laboratories, Inc. (“Plaintiff”), defendant Roxane Laboratories, Inc. (“Roxane” or “Defendant”) responds to each allegation of the Complaint as follows:

NATURE OF THE ACTION

1. To the extent paragraph 1 recites conclusions of law, no answer is required. Roxane filed an Abbreviated New Drug Application No. 200-652 (“Roxane’s ANDA”) with the U.S. Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, use or sale of Alosetron Hydrochloride tablets, Eq. 1 mg Base and 0.5 mg Base, a generic version of LOTRONEX[®] (“Roxane’s ANDA products”). On information and belief, as

of the filing date of Roxane's ANDA, U.S. Pat. No. 6,284,770 ("the '770 patent") was not listed in the electronic version of the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") under the Patent and Exclusivity Search Results for Alosetron Hydrochloride Tablets, Eq. 1 mg Base and 0.5 mg Base. Roxane admits that in December 2010, after the '770 patent was listed in the Orange Book, Roxane provided the FDA with a "Paragraph IV Certification [21 CFR 314.94(a)(12)(i)(A)(4)]" ("December pIV certification"), which states the '770 patent "is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of" Roxane's ANDA products. Roxane also admits that in December 2010 Roxane provided its "Patent Notice Pursuant to § 505(j)(2)(ii) [21 USC § 355(j)(2)(B)(ii)]" regarding its pIV certification ("December Notice Letter") to Plaintiff. Roxane denies the remaining allegations in paragraph 1 of the Complaint.

2. Roxane admits that the Complaint sets forth Plaintiff's allegations that Roxane infringes the '770 patent. Roxane also admits that this action arises under the patent laws of the United States of America and under the Federal Food, Drug and Cosmetics Act (the "FFDCA"). Roxane denies the remaining allegations in paragraph 2 of the Complaint.

THE PARTIES

3. Roxane is without sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 3 of the Complaint.

4. Roxane admits that it is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.

5. Roxane admits that it is registered to do business in the State of New Jersey. Roxane admits that it maintains a registered agent for service of process in New Jersey. Roxane

also admits that it sells generic pharmaceutical products, and that these products are sold in the State of New Jersey and various other parts of the United States. Roxane also admits that Roxane has litigated patent cases in the United States District Court for the District of New Jersey, and at least in one of those cases, Roxane asserted a counterclaim. Roxane denies the remaining allegations in paragraph 5 of the Complaint.

JURISDICTION AND VENUE

6. Roxane admits the allegations in paragraph 6 of the Complaint.

7. For the purposes of this litigation only, Roxane does not contest personal jurisdiction in this district. Roxane denies the remaining allegations in paragraph 7 of the Complaint.

8. The allegation in paragraph 8 of the Complaint is a conclusion of law to which no response is required. To the extent a response is required, Roxane does not contest venue in this district.

THE PATENT IN SUIT

9. Roxane admits that what appears to be a true and correct copy of the ‘770 patent and a reexamination certificate thereof are attached as Exhibit A to the Complaint. Roxane admits that, on its face, the ‘770 patent shows an issue date of September 4, 2001 and identifies Allen Wayne Mangel and Allison Ruth Northcutt as the inventors and is entitled “Medicaments For The Treatment Of Non-Constipated Female Irritable Bowel Syndrome.” Upon information and belief, Roxane admits that the ‘770 patent was subject to reexamination proceedings before the United States Patent and Trademark Office (“USPTO”). Roxane admits that, on its face, the reexamination certificate attached to the Complaint shows an issue date of October 19, 2010. Roxane denies the remaining allegations in paragraph 9 of the Complaint.

THE LOTRONEX® DRUG PRODUCT

10. Upon information and belief, Roxane admits that as of February 24, 2011, the Orange Book identifies Plaintiff as the holder of an approved New Drug Application for Alosetron Hydrochloride Tablets, Eq. 1 mg Base and 0.5 mg Base. Upon information and belief, Roxane admits that the February 24, 2011 Orange Book identifies the proprietary name of Alosetron Tablets as LOTRONEX®. Upon information and belief, Roxane admits that the reexamination certificate attached to the Complaint names Plaintiff as the assignee of the '770 patent. Roxane states that the reexamined claims of the '770 patent speak for themselves and otherwise denies the allegations pertaining thereto in paragraph 10 of the Complaint.

11. On information and belief, Roxane admits that as of February 24, 2011, the Orange Book lists the '770 patent under the Patent and Exclusivity Search Results for Alosetron Hydrochloride Tablets, Eq. 1 mg Base and 0.5 mg Base. Roxane denies the remaining allegations in paragraph 11 of the Complaint.

ACTS GIVING RISE TO THIS SUIT

12. Roxane admits that it submitted to the FDA an ANDA seeking approval to engage in the commercial manufacture, use or sale of Roxane's ANDA products. Roxane admits that as of the filing date of Roxane's ANDA, the '770 patent was not listed in the Orange Book with respect to Alosetron Hydrochloride Tablets, Eq. 1 mg Base and 0.5 mg Base. Roxane denies the remaining allegations in paragraph 12 of the Complaint.

13. Roxane admits that after the '770 patent was listed in the Orange Book, Roxane provided the FDA with the December pIV certification that states the '770 patent "is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of" Roxane's ANDA products. Roxane denies the remaining allegations in paragraph 13 of the Complaint.

14. Roxane admits that in December 2010, Roxane provided its December Notice Letter to Plaintiff. Roxane also admits that what appears to be a true and correct copy of the December Notice Letter is attached as Exhibit B to the Complaint. Roxane states that the December Notice Letter speaks for itself, and otherwise denies the remaining allegations in paragraph 14 of the complaint

15. To the extent paragraph 15 recites conclusions of law, no answer is required. Roxane denies the remaining allegations in paragraph 15 of the Complaint.

16. To the extent paragraph 16 recites conclusions of law, no answer is required. Roxane denies the remaining allegations in paragraph 16 of the Complaint.

17. Roxane admits that on approximately January 7, 2011, Roxane received a letter dated January 6, 2011 from F. Dominic Cerrito regarding the December Notice Letter. Prometheus filed this action on January 14, 2011 and served Roxane with a summons on January 20, 2011. In January 2011, Roxane provided the FDA with a "Paragraph IV Certification [21 CFR 314.94(a)(12)(i)(A)(4)]," which states the '770 patent "is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of" Roxane's ANDA products. In January 2011, Roxane also provided Prometheus with a "Patent Notice Pursuant to § 505(j)(2)(B)(ii) [21 U.S.C. § 355(j)(2)(B)(ii)]," addressing the reexamined claims of the '770 patent. Roxane denies the remaining allegations in paragraph 17 of the Complaint.

COUNT I

18. Roxane repeats and realleges paragraphs 1-17 as set forth herein.

19. Roxane denies the allegations in paragraph 19 of the Complaint.

20. Roxane denies the allegations in paragraph 20 of the Complaint.

21. Roxane repeats and realleges paragraph 17 as set forth herein. Roxane denies the remaining allegations in paragraph 21 of the Complaint.

22. Roxane denies the allegations in paragraph 22 of the Complaint.

23. Roxane denies the allegations in paragraph 23 of the Complaint.

24. Roxane repeats and realleges paragraph 17 as set forth herein. Roxane denies the remaining allegations in paragraph 24 of the Complaint.

COUNT II

25. Roxane repeats and realleges paragraphs 1-24 as set forth herein.

26. Roxane denies the allegations in paragraph 26 of the Complaint.

27. Roxane repeats and realleges paragraph 13 as set forth herein. Roxane denies the remaining allegations in paragraph 27 of the Complaint.

28. Roxane repeats and realleges paragraph 14 as set forth herein. Roxane states that the Notice Letter speaks for itself, and otherwise denies the remaining allegations in paragraph 28 of the Complaint.

29. Roxane admits there is a justiciable controversy in this case that arises under the patent laws of the United States of America and under the FFDCA. Roxane denies the remaining allegations in paragraph 29 of the Complaint.

30. Roxane denies the allegations in paragraph 30 of the Complaint.

31. Roxane denies the allegations in paragraph 31 of the Complaint.

32. Roxane denies the allegations in paragraph 32 of the Complaint.

33. Roxane denies the allegations in paragraph 33 of the Complaint.

34. Roxane denies the allegations in paragraph 34 of the Complaint.

35. Roxane denies the allegations in paragraph 35 of the Complaint.

ANSWER TO PRAYER FOR RELIEF

36. Roxane denies that Plaintiff is entitled to the judgment and relief prayed for in paragraphs (A) through (O) of the Complaint.

FIRST DEFENSE

37. Count I of the Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

38. The commercial manufacture, use, sale, offer for sale or importation of Roxane's ANDA products does not and will not infringe any valid or enforceable claim of the '770 patent, either literally or under the doctrine of equivalents.

THIRD DEFENSE

39. Based upon information presently available, and without prejudice to further amendment upon information found during discovery, all of the claims of the '770 patent that could be asserted against Roxane based on Roxane's ANDA are invalid for reasons including but not limited to the failure to meet the conditions for patentability set out at in 35 U.S.C. §§ 101 *et seq.* and under the judicially established doctrine of obviousness-type double patenting.

FOURTH DEFENSE

40. Roxane reserves the right to raise further additional defenses as may be available upon the facts to be developed in discovery and under applicable substantive law.

WHEREFORE, Roxane prays that:

1. The Court enter judgment in Roxane's favor;
2. Plaintiffs' claims be dismissed with prejudice;
3. Plaintiffs be awarded nothing in damages, costs, or fees; and,

4. Defendant be awarded costs of suit and such other relief as may be just and appropriate.

Dated: February 24, 2011

Respectfully submitted,

s/ Mark S. Olinsky

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